

Appl. No. : 09/447,227
Filed : November 22, 1999

REMARKS

Claims 33-35, 38, 39, 41, 42, 48, 49, and 54-83 are pending in this application.

Interview

Applicants thank Examiner Nasser for the courteous and helpful interview conducted with Applicants' representative, Laura Johnson, on November 28, 2006.

Claim Rejection - 35 U.S.C. §103(a) – Rhodes *et al.* in view of Allen *et al.* and Picha

Claims 33-35, 38, 41, 42, 48, 49, and 54-83 have been rejected under 35 U.S.C. §103(a) as obvious over Rhodes *et al.* (WO92/13271) in view of Allen *et al.* (US 5,322,063) and Picha (US 5,706,807). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See* M.P.E.P. § 2143.01 V. *See also, In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (stating that “The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.”).

Claim 34 recites a method of measuring glucose in a biological fluid comprising, *inter alia*, the steps of “providing an implantable device comprising a sensor capable of continuous glucose sensing, said sensor having a protruding interface tip ...” and “implanting said device subcutaneously into tissue of said host so as to elicit a foreign body capsule as a result of the response of said host to the introduction of said implantable device, said sensor interface tip communicating with the tissue of said host such that said tip is anchored by tissue ingrowth in said foreign body capsule.” Claim 38 recites a method of monitoring glucose levels, comprising, *inter alia*, the step of “providing ... a device comprising ... a sensor capable of continuous glucose sensing, said sensor comprising a sensor interface tip ... wherein said sensor interface tip protrudes beyond a plane of the body to assist in formation of vasculature” As Applicants note in the instant specification, a protruding sensor tip offers advantages, namely, “protrusion is

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believed to assist in the formation of vasculature in the sensor interface dome 30 region.” See specification as filed, page 13, lines 20-22.

Rhodes *et al.* teaches an implantable sensor wherein the sensing region is recessed from the housing. See page 16 of Rhodes *et al.*, which specifies that “to protect the membrane from any mechanical force ... it is recessed within the case and protected by the screen” As depicted in Figure 2, Allen *et al.* teaches a planar glucose sensor with a membrane layer overlying an electrode region on one side of the sensor. The only combination of Allen *et al.* and Rhodes *et al.* consistent with the teachings of both references would involve a configuration wherein the membrane layer of Allen *et al.* is recessed within the body of the Rhodes sensor and protected by a screen. A configuration wherein the membrane layer of Allen *et al.* protrudes beyond the body of the sensor, and thus is not protected from mechanical force, would be contrary to the teachings of Rhodes *et al.* Accordingly, Allen *et al.* destroys Rhodes *et al.* Picha is cited as teaching a device including an angiogenic layer surrounding an implantable device; however, Picha does not teach or suggest a protruding sensor tip.

Because Allen *et al.* destroys Rhodes *et al.*, the proposed modification of Rhodes *et al.* is improper and is not sufficient to establish a *prima facie* case of obviousness based on the combination of Rhodes *et al.*, Allen *et al.*, and Picha. Applicants therefore respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. §103(a) – Allen *et al.* in view of Rhodes *et al.* and Picha

Claims 33-35, 38, 41, 42, 48, 49, and 54-83 have been rejected under 35 U.S.C. §103(a) as obvious over Allen *et al.* (US 5,322,063) in view of Rhodes *et al.* (WO92/13271) and Picha (US 5,706,807). A *prima facie* case of obviousness cannot be established if the disclosure of the cited prior art, when taken as a whole, teaches away from the claimed invention. See, e.g., M.P.E.P. § 2141.02.

The Office Action asserts that it would have been obvious to modify Allen *et al.* to use the membrane structure of Rhodes *et al.*, to improve the accuracy of measurement, and that it would have been obvious, in view of Picha which discloses an angiogenic layer surrounding a sensing device, to modify the combination to engulf the entire device in Dacron. Applicants respectfully disagree. In combining the teachings of Allen *et al.* with Rhodes *et al.*, the resulting device would have the membrane structure of Rhodes *et al.* covering the electrode region of

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Allen *et al.* However, Rhodes *et al.* teaches protection of the membrane from mechanical forces, which is incompatible with a configuration wherein the membrane covers a protruding sensor tip – a configuration that would expose the membrane to mechanical forces, not protect it from mechanical forces.

Because the teachings of Rhodes *et al.* are directed to protecting the membrane from mechanical forces, they are incompatible with teachings of any sensor configuration employing a protruding sensing tip covered by the membrane. A *prima facie* case of obviousness therefore cannot be made based on the combination of Allen *et al.*, Rhodes *et al.*, and Picha, and Applicants respectfully request withdrawal of the rejection.

Conclusion

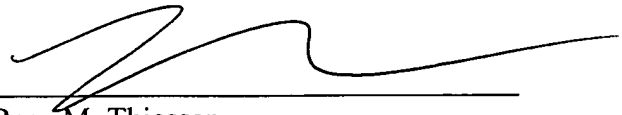
In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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